UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,795	12/27/2001	Michael J. Brubaker	P02971	1325

7590 01/15/2004

BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,795	BRUBAKER, MICHAEL J.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/378,374. Although the conflicting claims are not identical, they are not patentably distinct from each other. Copending Application No. 10/378,374 claims a device that is structurally similar wherein the device comprises a drug core, a

unitary cup and a permeable plug. The drugs delivered by the device are the same or similar as those of the instant claims. The materials used to produce the cup and the plug are also the same or similar to those used in the instant claims. Finally, the methods of delivery and methods of manufacturing of the applications are the same or similar. Therefore, at the time the invention was made it would have been obvious to use different materials to form the unitary cup or the permeable plug to provide the same desired result of a sustained release implantable device.

Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/023,391. Although the conflicting claims are not identical, they are not patentably distinct from each other. Copending Application No. 10/023,391 claims the same or similar sustained release drug delivery device comprising a drug core, a unitary cup and a permeable plug. The materials used for the unitary cup and the permeable plug are the same or similar materials and the drugs released by the composition are the same. The drug core can also contain a plurality of active agents. Copending Application No. 10/023,391 also claims methods of providing controlled or sustained release to particular location in/on the patient. Finally, the application also teaches a method of manufacturing such a device or composition. Therefore, at the time the invention was made it would have been obvious to use different materials to form the unitary cup or the permeable plug to provide the same desired result of a sustained release implantable device.

Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-47 of copending Application No. 10/035,095. Although the conflicting claims are not identical, they are not patentably distinct from each other. Copending Application No. 10/035,095 claims the same or similar sustained release drug delivery device comprising a drug core, a unitary cup, a permeable plug and a second active drug. The materials used for the unitary cup and the permeable plug are the same or similar materials and the drugs released by the composition are the same. The drug core can also contain a plurality of active agents. Copending Application No. 10/023,391 also claims methods of providing controlled or sustained release to particular location in/on the patient. Finally, the application also teaches a method of manufacturing such a device or composition. Therefore, at the time the invention was made it would have been obvious to use different materials to form the unitary cup or the permeable plug to provide the same desired result of a sustained release implantable device.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5378475). Smith teaches a sustained release drug delivery device comprising a drug core surrounded by a drug impermeable player that partially coats the drug core and a second layer that completely coats the core plus the first layer wherein the second layer is permeable to the drug (Col. 4, lines 15-45). The device further comprises a suture tab (Col. 4, lines 44-57). Various drugs can be contained within the core including antiglaucoma drugs, antibiotics, antivirals and antibacterials (Col. 5, line 4 – Col. 6, line 25). The first layer can be made from impermeable polymers and silicone rubbers (Col. 6, lines 30-66). The second layer is permeable to the drug and can be made of various permeable polymers, celluloses and/or polyvinyl alcohols (Col. 8, lines 49-68). The device can be implanted in the eye (Col. 9, lines 42-53). Further, the release rate of the device is controlled by how much of the drug core is coated with the impermeable coating (Col. 7, lines 25-51). Smith does not teach the permeable portion of the device is prefabricated or that the suture tab has a hole through it in the proximal end. Smith further does not expressly teach that the suture tab is made from silicone.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a device comprising a drug core surrounded at least partially by a drug impermeable layer and a second portion that is permeable to the drug wherein the device has a sustained release rate. It is the position of the Examiner that no criticality is seen in the hole in the suture tab or the fact that the permeable portion of the device is prefabricated. The suture tab material also does not appear to critical to the invention. The references teaches various polymer and materials that can be used in the device, one being silicone. The device is in the same filed of endeavor, has the same elements, and is used in the same manner to achieve the same results. Any difference is a matter of degree and not of kind.

One of ordinary skill in the art would have been motivated to do this to provide a sustained release ocular implant that is suitable to release the drug over a period of time in a fixed location. It would be obvious to use any of the suitable materials to create the first layer or the second or the suture tab to achieve the same desired result of a sustained release implantable device. Again, no criticality is placed in the suture tab being silicone as opposed to the PVA recited by the art, or the limitation that the tab must have a hole or the permeable portion being prefabricated.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703)

308-8869. As of February 5, 2004, the Examiner can be reached at (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600